REMARKS

After entry of the present amendment, claims 1-9, 12, 14-26, 32-36 and 41-42 are pending in the application. Claims 1-9, 12, 14-26 and 32-36 are herein amended. Claims 10, 11, 13, 27-31 and 37-40 have been canceled.

New claims 41 and 42 have been added. Applicants submit support for new claims 41 and 42 can be found at least in original claims 4 and 5.

Additionally, the specification has been amended to correct a minor typographical error. Applicants submit that no new matter is added by these amendments.

Specification Amendments

Applicants herein amend the specification at page 24, line 18, to remove the word "although". Applicants submit this amendment corrects a typographical error in the specification, specifically the duplication of the word "although".

Claim Objections

Claim 37 was objected to as being in improper form because a multiple dependent claim cannot depend from any other multiple

dependent claims. As claim 37 has been canceled herein, Applicants submit the rejection has been rendered moot.

Rejections under 35 USC §112

Claims 1-40 were rejected as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the Examiner notes the word "the" as used in claims 1 and 35, and the claims dependent therefrom, lacks antecedent basis. Applicants herein amend claims 1 and 35, and the claims dependent therefrom, by either deleting the term "the" or replacing it with "a" or "an" as appropriate. By these amendments, Applicants believe the present rejection has been overcome.

The Examiner notes the term "Sandwich assay" as used in claims 2-34 should be replaced with "The sandwich assay", and the term "Kit" as used in claims 36-38 should be replaced with "The kit". Applicants have amended claims 2-9, 12, 14-26 and 32-34 to recite "The sandwich assay" and have amended claim 36 to recite "The kit", as suggested by the Examiner. Claims 37 and 38 have been canceled herein. Accordingly, it is believe the present rejection has been overcome.

In claims 4, 5, 12, 14, and 32 the Examiner notes improper Markush language is used. Accordingly, Applicants herein amend claims 4, 12, 14 and 32 to recite "selected from . . . or" as suggested by the Examiner, and submit this rejection has been overcome.

In claim 12, the Examiner points out that there is a typographical error. Specifically, the term "reception" should recite "receptin". Applicants wish to thank the Examiner pointing out this typographical error and herein amend claim 12 as suggested by the Examiner.

The Examiner further states that in claims 29 and 30, the term "the oligonucleotide" lacks antecedent basis. Claims 29 and 30 are canceled herein, thus rendering this rejection moot.

Additionally, claims 38-40 were rejected as the claims do not further limit any components of the kit. Claims 38-40 are canceled herein, thereby rendering the present rejection moot.

Rejections under 35 USC §102

Claims 1-10 and 32-40 were rejected under 35 USC §102(b) as being anticipated by U.S. Patent No. 4,595,655 to Self. Additionally, claims 1-8, 10 and 32-40 were rejected under 35 USC §102(b) as anticipated by U.S. Patent No. 5,284,778 to Canfield, et al. Claims 1-7, 9, 10, 32, 33 and 35-40 were also

rejected under 35 USC §102(b) as anticipated by EP 166,623 to Thompson, et al. Claims 1-4, 6-10 and 27-40 were rejected under 35 USC §§102(a) and 102(e)(1) as being anticipated by WO 01/81924 to Drukier.

Claims 1 and 35, and the claims dependent therefrom, have been amended to recite "wherein at least one of the first and second affinity ligands is a naturally occurring bacterial receptin, a domain thereof, or an engineered protein". Support for these amendments can be found at least in originally presented claims 11 and 13. Additionally, support for naturally occurring bacterial receptins, domains thereof, and engineered proteins can be found in the specification at page 13, line 14 to page 14, line 37. Accordingly, no new matter is added by this amendment.

None of the above-mentioned references teach or suggest a sandwich assay having a first and second affinity ligand wherein at least one of the first and second affinity ligands is a naturally occurring bacterial receptin, a domain thereof, or an engineered protein. Accordingly, Applicants submit that none of the references, either taken alone or in any combination, disclose or suggest the sandwich assay method of the present claimed invention. Therefore, Applicants submit the present

rejection has been overcome and respectfully request the Examiner withdraw the rejection.

Claims 1-4, 6-8, 10-26, 32 and 35-40 were rejected under 35 USC §102(b) as being anticipated by Hansson, et al. Applicants respectfully traverse this rejection.

Hansson, et al. disclose selecting a novel binding protein, Z-affibody, showing selective binding to the RSV G protein from a combinatorial library of variants of a small α-helical protein domain, Z, derived from staphylococcal protein A (SPA) by using phage-display technology.

In Hansson, et al. the most relevant experiments are epitope mapping studies in a Biacore™ instrument, in which a target-binding Z molecule is immobilized on a sensor chip surface, a target molecule is applied, and an antibody known to interact with the target is applied thereafter. The antibody is applied in order to test whether or not the Z variant binds to the same epitope as the antibody, or if it binds to some other epitope. The experiments are carried out using purified protein preparations. These experiments are described on pages 242 and 245-246.

In contrast, the presently claimed invention is a sandwich assay for detecting the presence of a target molecule in a sample. As recited in claim 1 of the present application, the

sample comprises a complex biological fluid. The claimed sandwich assay requires indirect detection of a target molecule through the detection of the presence of the second affinity ligand.

Hansson, et al. does not disclose or suggest the indirect detection of a target molecule through the detection of the presence of a second affinity ligand. In fact, Applicants submit that detection of a second affinity ligand in the experiments disclosed in Hansson, et al. to detect the presence of a target molecule is not needed and such step would be redundant since the target molecule is detected instantaneously with the use of the surface plasmon resonance-based Biacore™ instrument.

Furthermore, Applicants submit Hansson, et al. does not disclose or suggest the detection of a target molecule in a sample comprising a complex biological fluid. In contrast, the experiments in Hansson, et al. are carried out using purified protein preparations.

Accordingly, Applicants submit the present rejection has been overcome and respectfully request the Examiner withdraw the rejection.

Claims 1-4, 6-8, 10-26, 32 and 35-40 were rejected under 35 USC §102(b) as being anticipated by International Patent

Application No. WO 00/63243 to Ljungqvist, et al. Applicants respectfully traverse this rejection.

Ljungqvist, et al. discloses modified polypeptides which are derivatives of the B domain or Z domain from staphylococcal protein A (SPA). Between 1 and 20 amino acid residues of the B or Z domain have been substituted by other amino acid residues. The substitution was made without substantial loss of the basic structure and stability of the B or Z domain, and the substitution results in interaction capacity of the polypeptide with at least one domain of human Factor VIII protein.

In Ljungqvist, et al., the most relevant experiments are epitope mapping studies using a Biacore™ instrument, in which a target-binding Z molecule is immobilized on a sensor chip surface, a target molecule is applied, and an antibody known to interact with the target is applied thereafter. The antibody was applied in order to test whether or not the Z variant binds to the same epitope as the antibody, or if it binds to some other epitope. The experiments are carried out using purified protein preparations. These experiments are described on pages 11-13 and 16-17.

In contrast, the presently claimed invention is a sandwich assay for detecting the presence of a target molecule in a sample. As recited in claim 1 of the present application, the

sample comprises a complex biological fluid. The claimed sandwich assay requires indirect detection of a target molecule through the detection of the presence of the second affinity ligand.

Ljungqvist, et al. does not disclose or suggest the indirect detection of a target molecule through the detection of the presence of a second affinity ligand. In fact, Applicants submit that detection of a second affinity ligand in the experiments disclosed in Ljungqvist, et al. to detect the presence of a target molecule is not needed and such step would be redundant since the target molecule is detected instantaneously with the use of the surface plasmon resonance-based Biacore™ instrument.

Furthermore, Applicants submit Ljungqvist, et al. does not disclose or suggest the detection of a target molecule in a sample comprising a complex biological fluid. In contrast, the experiments in Ljungqvist, et al. are carried out using purified protein preparations.

Accordingly, Applicants submit the present rejection has been overcome and respectfully request the Examiner withdraw the rejection.

Applicants submit that the claims are now in condition for allowance and a prompt Notice of Allowance is respectfully solicited.

If the Examiner believes a telephone conference would aid in the continued prosecution of this application, the Examiner is invited and encouraged to contact Applicants' representative at the telephone number listed below.

Any fees due with this correspondence may be charged to Deposit Account 23-1665 under Customer Number 27267.

Respectfully submitted,

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